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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,223	04/08/2004	G.R. Barrie Webster	84676-302	7119

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EXAMINER	
SPIVACK, PHYLLIS G	
ART UNIT	**PAPER NUMBER**
1614	

DATE MAILED: 07/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/820,223	WEBSTER ET AL.	
	Examiner	Art Unit	
	Phyllis G. Spivack	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 May 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-6 and 8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 2, 4-6, 8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Applicants' Response filed May 9, 2006 is acknowledged. Claims 3 and 7 are canceled. Claims 1, 2, 4-6 and 8 remain under consideration.

The objection to the disclosure that was set forth in the last Office Action is withdrawn following editorial corrections.

Claims 2 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Claims 2 and 6 recite the limitation "2-10 parts Δ^8-tetrahydrocannabinol to 1 part cannabidiol". There is insufficient antecedent basis for this limitation in the independent claims from which they depend.

Applicants' arguments with respect to the rejections of claims 1, 2, 5 and 6 under 35 U.S.C. 102(b) and of claims 1-8 under 35 U.S. C. 103, set forth in the last Office Action, have been considered but are moot in view of the new grounds of rejection.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mueller, A., US 2004/0049059, in view of Russo, E.B., Pain Management.

Mueller teaches a pharmaceutical composition for oral administration in the form of an extract comprising 1 part cannabidiol to 2 parts Δ^8-tetrahydrocannabinol which

may be employed as an antiemetic. See page 2, [0021], page 3, [0037], and Table 4, page 8. The open language of the present claims allows for the inclusion of any number of additional active ingredients. Mueller fails to teach concentration ranges of 2-10 mg Δ^8-tetrahydrocannabinol and 0.2-20 mg cannabidiol. However, Russo provides state of the art background information that dosing of therapeutic cannabinoids must be titrated to the individual patient's needs, particularly in view of the highly lipophilic nature of Δ^8-tetrahydrocannabinol and cannabidiol. The commercial synthetic product, Marinol, is available as 2.5, 5 and 10 mg capsules. For chemotherapy-induced nausea and vomiting, 2.5-5 mg orally is the recommended dose. Thus, given these guidelines, one skilled in the art would have been motivated to prepare a pharmaceutical composition wherein the determination of an optimal ratio of the active agents, as well as optimal dosages, are found through no more than routine experimentation.

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abrahamov et al., Life Sciences, in view of Russo, E.B., Pain Management, Karniol and Carlini, Psychopharmacologia, Karniol et al., Eur. J. Pharma., Zuardi et al., Psychopharmacology, and Hollister and Gillespie, Clin. Pharmacol. Ther.

Abrahamov teaches the effective oral administration of Δ^8-tetrahydrocannabinol (Δ^8-THC) to treat the nausea and vomiting that occurs following cancer chemotherapy in a pediatric population. Cannabidiol is disclosed to be biologically inactive and exhibits no psychoactive effect. Abrahamov fails to include administration of cannabidiol (CBD) and does not disclose dosage ranges. However, motivation is provided through the

teachings of Karniol, Zuardi and Hollister to include CBD in combination with Δ^8-THC. It would have been obvious in the absence of evidence to the contrary to administer a pharmaceutical composition comprising both Δ^8-THC and CBD because CBD blocks the excitatory effects of Δ^9-THC. CBD attenuates side effects of Δ^9-THC, such as pulse rate acceleration, time production impairment and psychological disturbances. CBD decreases the anxiety effect associated with Δ^9-THC. CBD retards and prolongs the duration of effect of Δ^9-THC. Δ^8-THC is a double bond isomer of Δ^9-THC and is a cannabinoid with lower psychotropic potency than Δ^9-THC. Russo provides state of the art background information that dosing of therapeutic cannabinoids must be titrated to the individual patient's needs, particularly in view of the highly lipophilic nature of Δ^8-tetrahydrocannabinol and cannabidiol. See page 368. The commercial synthetic product, Marinol, is available as 2.5, 5 and 10 mg capsules. For chemotherapy-induced nausea and vomiting, 2.5-5 mg orally is the recommended dose. The determination of an optimal ratio of the active agents, as well as optimal dosages, are parameters well within the purview of those skilled in the oncology art through no more than routine experimentation.

No unexpected results are noted. Accordingly, the claims are denied.

Applicants' Amendment necessitated the new ground of rejection presented in this Office Action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire THREE MONTHS from the mailing date of this Action. In the event a first reply is filed within TWO MONTHS of the mailing date of this Final Action and the Advisory Action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this Final Action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Ardin Marschel, can be reached 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

July 15, 2006

Phyllis Spivack

PHYLLIS SPIVACK
PRIMARY EXAMINER